## REMARKS/ARGUMENTS

## I. STATUS OF THE CLAIMS

Claims 1-32 are pending. Claims 18-32 are withdrawn from consideration as being directed to a non-elected subject matter. Claims 1-17 are currently being prosecuted.

## II. REJECTION UNDER 35 U.S.C. §102(b)

Claims 1-17 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Kong *et al.*, (1999) *Marine Pollution Bull.* 38(9):802-808.

### A. Kong *et al.* does not teach or disclose all of the elements of independent claim 1

The Examiner cites Kong *et al.* as teaching a method of testing the integrity of primers in a multiplex amplification reaction, the amplification reaction comprising primers sufficient to amplify at least two different target sequences. Specifically, the Examiner alleges that Kong *et al.* teaches providing in a mixture the primers and a single stranded polynucleotide sequence comprising the sequences of the primers and amplifying the polynucleotide sequence. *See*, page 3 of the Office Action, citing to page 806, col. 2 of Kong *et al.* Furthermore, the Examiner alleges that Kong *et al.* teaches detecting the presence or absence of the amplified polynucleotide, thereby testing the integrity of the primers in the amplification reaction. *See*, page 3 of the Office Action, citing to Figure 2 of Kong *et al.*

Applicants respectfully traverse the rejection. Claim 1 recites a method for testing the integrity of primers in a multiplex amplification reaction, where the reaction comprises primers sufficient to amplify *at least two different target sequences*. Kong *et al.* teaches a series of standard PCR reactions in which a specific target sequence is amplified in each reaction. Kong *et al.* does not teach an amplification reaction comprising primers sufficient to amplify *at least two different target sequences* from a single-stranded polynucleotide as recited in claim 1. Moreover, even if multiplex amplification was applied to the primers of Kong *et al.*, this would not have resulted in ***a*** single-stranded polynucleotide sequence comprising

sequences or subsequences of the *primers used to amplify at least two different targets*. Accordingly, the present claims are novel and non-obvious.

***i. Kong et al. did not teach using primers to amplify at least two different targets***

Kong *et al.* discloses a method for determining the specificity of a specific primer pair to a specific target sequence in a standard PCR reaction, *not* a method for determining the integrity of primers in a multiplex PCR reaction, e.g., a reaction comprising primers sufficient to amplify at least two different targets. Therefore, Kong *et al.* does not teach "providing in a mixture the primers" where "the primers" are sufficient to amplify at least two different targets, as recited in claim 1. Accordingly, Kong *et al.* cannot anticipate the claims.

***ii. Kong et al. did not teach or suggest using a polynucleotide sequence comprising primers sufficient to amplify at least two different targets***

Claim 1 recites that the single-stranded polynucleotide comprises "the sequences of the primers, subsequences of the primers at least five nucleotides long, or complements of the sequences of the primers." The Examiner has interpreted this language to read on simple PCR, arguing that an amplified target necessarily comprises primer sequences or their complement. The Examiner has not understood the claimed invention. In fact, "the primers" refers to "primers sufficient to amplify at least two different target sequences" as recited earlier in the claim. Thus, claim 1 requires that the "single-stranded polynucleotide" comprise at least three and likely at least four primers when PCR is used to amplify two targets, wherein a first set of two primers are used to amplify a first target and a second set of two primers is used to amplify the second target. This, of course, is merely one example of simple multiplex PCR, but it illustrates the difference between simple PCR, or even multiplex PCR, and the control polynucleotide recited in claim 1. In this example, *in addition to possible targets*, the mixture comprises a single-stranded polynucleotide comprising each set (e.g., all four) primer sequences, subsequences or complements thereof. In contrast, simple multiplex PCR includes at most two different target polynucleotides, one possibly comprising one set of primer sequences and a second target

polynucleotide comprising the second set of primer sequences, *but not* one polynucleotide comprising all four primer sequences (or subsequences or complements thereof).

As recited in claim 1, the single-stranded polynucleotide includes sequences, subsequences or complements of *all* of the primers necessary to amplify at least two different targets. This sort of control is neither taught nor suggested by the Kong *et al.* reference. Therefore, Kong *et al.* does not anticipate the claims.

***iii. Conclusion***

In view of the above, the Applicants respectfully request that the Examiner withdraw the rejection.

## CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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